

# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference MLC/LCW/2872PC	<b>FOR FURTHER ACTION</b>	See item 4 below
International application No. PCT/GB2006/003425	International filing date ( <i>day/month/year</i> ) 15 September 2006 (15.09.2006)	Priority date ( <i>day/month/year</i> ) 15 September 2005 (15.09.2005)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant SMITH & NEPHEW, PLC		

1.	This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 <i>bis</i> .1(a).																								
2.	This REPORT consists of a total of 9 sheets, including this cover sheet.  In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.																								
3.	<p>This report contains indications relating to the following items:</p> <table style="width: 100%;"> <tr> <td style="width: 10%; text-align: center;"><input checked="" type="checkbox"/></td> <td style="width: 30%;">Box No. I</td> <td style="width: 60%;">Basis of the report</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>	<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input checked="" type="checkbox"/>	Box No. II	Priority	<input checked="" type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input checked="" type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input checked="" type="checkbox"/>	Box No. VIII	Certain observations on the international application
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4.	The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).																								

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Date of issuance of this report 18 March 2008 (18.03.2008)
Facsimile No. +41 22 338 82 70	Authorized officer  <div style="text-align: center; font-weight: bold;">Dorothee Mülhausen</div>
e-mail: pt01.pct@wipo.int	

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

# PCT

## WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

To:

see form PCT/ISA/220

Date of mailing  
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference see form PCT/ISA/220	<b>FOR FURTHER ACTION</b> See paragraph 2 below
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International application No. PCT/GB2006/003425	International filing date (day/month/year) 15.09.2006	Priority date (day/month/year) 15.09.2005
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International Patent Classification (IPC) or both national classification and IPC  
INV. A61M27/00 A61M1/00

Applicant  
SMITH & NEPHEW, PLC

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application



2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

<p>Name and mailing address of the ISA:</p>  <p>European Patent Office - Gitschiner Str. 103 D-10958 Berlin Tel. +49 30 25901 - 0 Fax: +49 30 25901 - 840</p>	<p>Date of completion of this opinion</p> <p>see form PCT/ISA/210</p>	<p>Authorized Officer</p> <p>Rolland, Philippe</p> <p>Telephone No. +49 30 25901-274</p> 
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**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/GB2006/003425

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**Box No. I Basis of the opinion**

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1. With regard to the **language**, this opinion has been established on the basis of:
  - ☒ the international application in the language in which it was filed
  - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material:
    - ☐ a sequence listing
    - ☐ table(s) related to the sequence listing
  - b. format of material:
    - ☐ on paper
    - ☐ in electronic form
  - c. time of filing/furnishing:
    - ☐ contained in the international application as filed.
    - ☐ filed together with the international application in electronic form.
    - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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**Box No. II Priority**

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1. ☒ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43*bis*.1 and 64.1) is the claimed priority date.
2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/GB2006/003425

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**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

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The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

- ☐ the entire international application
- ☒ claims Nos. 21,22,23,24,26,35

because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international search (*specify*):
- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☒ the claims, or said claims Nos. 21,22,23,24,26 are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

**see separate sheet**

- ☒ no international search report has been established for the whole application or for said claims Nos. 35
- ☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:
  - ☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
  - ☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
  - ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b).
- ☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
- ☐ See Supplemental Box for further details

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/GB2006/003425

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**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

Novelty (N)	Yes: Claims	26
	No: Claims	1-25,27-34
Inventive step (IS)	Yes: Claims	
	No: Claims	1-34
Industrial applicability (IA)	Yes: Claims	1-34
	No: Claims	

2. Citations and explanations

**see separate sheet**

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**Box No. VI Certain documents cited**

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1. Certain published documents (Rules 43bis.1 and 70.10)

and / or

2. Non-written disclosures (Rules 43bis.1 and 70.9)

**see form 210**

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**Box No. VII Certain defects in the international application**

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The following defects in the form or contents of the international application have been noted:

**see separate sheet**

**Re Item III.**

For the subject-matter of claim 35, rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy, applies.

Claim 35 relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the novelty, inventive step and industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

In addition, claims 21-24,26 are not fully supported by the description as required by Article 6 PCT, as no basis for their subject-matters could be found in the application as originally filed.

**Re Item V.**

1 Reference is made to the following document:

D1 : WO 2005/046761 A (SMITH & NEPHEW [GB]; BLOTT PATRICK LEWIS [GB]; GREENER BRYAN [GB]; HAR) 26 May 2005 (2005-05-26)

D2: WO 93/09727 A (UNIV WAKE FOREST [US]) 27 May 1993 (1993-05-27)

2 INDEPENDENT CLAIM 1

2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT. Document D1 discloses (the references in parentheses applying to this document):

"According to the present invention there is provided an apparatus for aspirating, irrigating and/or cleansing wounds (page 4 I.1-3), characterised in that it comprises

a) a fluid flowpath (page 4 I.4), comprising

i) a wound dressing (page 4 I.5), having a backing layer (page 4 I.6) and at least one inlet pipe for connection to a fluid supply tube (page 4 I.8-9), which passes through and/or under the backing layer (page 4 I.8-9) and at least one

outlet pipe for connection to a fluid offtake tube, which passes through and/or under the backing layer (page 4 l.10-11), at least one inlet pipe being connected to a fluid recirculation tube (page 4 l.15), and at least one outlet pipe being connected to a fluid offtake tube (page 4 l.15-16); and

ii) a means for fluid cleansing having at least one inlet port connected to a fluid offtake tube and at least one outlet port connected to a fluid recirculation tube (page 4 l.17-19);

b) a device for moving fluid through the wound dressing and means for fluid cleansing (page 4 l.23-24), and optionally or as necessary the fluid supply tube (page 4 l.23-24);

e) means for supplying physiologically active agents from cells or tissue to the wound (page 4 l.25 and page 6 l.12 "blood", the blood is a tissue and it contains cells: red blood cells, white blood cells and platelets); and

optionally or as necessary means for bleeding the flowpath, such that fluid may be supplied to fill the flowpath and supply physiologically active agents from cells or tissue to the wound and recirculated by the device through the flow path (page 4 l.25-29)."

2.2 The application does not meet the requirements of Article 6 PCT, because claim 1 is not clear.

The terms "optionally or as necessary" used in claim 1 is vague and unclear and leave the reader in doubt as to the meaning of the technical features to which they refer, thereby rendering the definition of the subject-matter of said claim unclear, Article 6 PCT, see also PCT Guidelines Chapter 5, 5.40.

### 3 DEPENDENT CLAIMS 2-34

Dependent claims 2-34 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and 33(3) PCT).

For the subject-matter of:

- Claim 2: see D1 page 4 l.6-7

- Claim 3: see D1 page 4 l.12-14
- Claim 4: see D1 page 4 l.5
- Claim 5: see D1 page 6 l.5-8
- Claim 6: see D1 page 6 l.10-25
- Claim 7: see D1 page 6 l.12 "blood"
- Claim 8: see D1 page 6 l.23-25, fibroblasts play a critical role in wound healing so they are present normally in acute or chronic wounds and keratinocytes are present as well for the reconstruction of the epidermis.
- Claim 9: see D1 page 16 l.15-20, and the product description of IV3000 (<http://www.smith-nephew.com/investors/portfolio/wound-IV3000.html>): "IV3000 dressings are made from a unique REACTIC™ film, which is **breathable** and significantly more permeable to water vapour than ordinary film."
- Claim 10: see D1 p.22 l.30 to p.23 l.2, Fig.5b "71", Fig.18b
- Claim 11: see D1 p.23 l.23-26
- Claim 12: see D1 Fig.5b "42" "46" "62", p.59 l.3-18
- Claim 13: see D1 p.3 l.13
- Claim 14: see D1 p.45 l.24-28
- Claim 15: see D1 Fig.28.
- Claim 16: see D1 Fig.28 "9", "6"
- Claim 17: see D1 Fig.28 "918"
- Claim 18: see D1 Fig.28 "12", "14", p.55 l.28-31
- Claim 19: see D1 p.73 l.11-14
- Claim 20: see D1 p.32 l.5-30
- Claim 21: see D1 p.5 l.30-33 and p.33 l.7-9
- Claim 22, 23: see D1 p.34 l.1-3
- Claim 24: see D1 p.21 l.8-31
- Claim 25: see D1 p.73 l.16-18
- Claim 26: see D1 p.22 l.10-13 and D2 p.5 l.13-24
- Claims 27, 28: see D1 claims 7,8
- Claim 29: see D1 claim 9
- Claim 30: see D1 claim 10
- Claim 31: see D1 p.46 l.20 to p.47 l.6
- Claim 32: see D1 p.43 l.6-27
- Claim 33: see D1 p.39 l.27 to p.40 l.11



- Claim 34: see D1 p.31 I.32-35

**Re Item VII.**

- 1.1 Independent claim 1 is not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).
- 1.2 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D1 is not mentioned in the description, nor is this document identified therein.
- 1.3 The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).